NIHON KOHDEN

MESSTECHNIK FÜR NEUROLOGIE, KARDIOLOGIE,
LABORDIAGNOSTIK UND INTENSIVÜBERWACHUNG

NIHON KOHDEN EUROPE GmbH, Raiffeisenstraße 10, D-61191 Rosbach v.d.H.

To all end-users of
NIHON KOHDEN Automated External Defibrillators AED-2100K series

Rosbach v.d.H., December 2016

Subject: **Important FIELD SAFETY NOTICE**

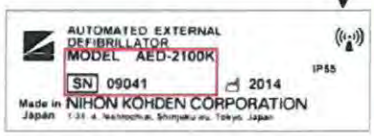
Information about a Field Safety Corrective Action for NIHON KOHDEN automated external defibrillators *cardiolife* AED-2100K
FSCA Ref. "AED-2100K/2016/1"

Dear Valued Customer,

With this Field Safety Notice (FSN) we want to inform you about a potential malfunction of specific LOTs of NIHON KOHDEN Automated External Defibrillators series *cardiolife* AED-2100K.

You get this FSN because you received at least one potential affected unit from your NIHON KOHDEN Representative.

The potential affected units can be identified by the serial number which is located on the product identification label at the backside of the AED.



AED-2100K with status indicator

Please make sure that all potential users in your facility are informed about this Field Safety Notice! For public access AEDs please pass this information to the person responsible for the AED!

Please confirm by returning attached receipt of this Field Safety Notice!

Description of the potential malfunction:
NIHON KOHDEN Automated External Defibrillators series *cardiolife* AED-2100K performs an internal self-test every day and displays the result on the status indicator. During our post marketing surveillance we found that there is a potential risk for a limited number of *cardiolife* AED-2100K that the power could not turned off after the self-test was completed and the battery gets discharged within one day in very rare cases. If so, the status indicator remains to lit "red" but no alarm sound is generated. As result there is the potential risk of about 0.0006% that the defibrillation is not available when required because of an empty battery.

Advise to users:
Please check the status indicator during your daily visual inspection carefully and contact your NIHON KOHDEN Representative when showing an abnormal status.

Corrective action:
An improved software version 02-02 eliminates the potential malfunction.

Based on our product tracking we found that we have delivered potential affected Automated External Defibrillators series *cardiolife* AED-2100K to you. You will find a detailed list of affected products attached to this Field Safety Notice!

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Raiffeisenstraße 10
61191 Rosbach v.d.H.
Telefon: 0 60 03 / 8 27-0
Telefax: 0 60 03 / 8 27-5 99

Vertrieb Deutschland:
Albert-Einstein-Ring 9
14532 Kleinmachnow
Telefon: 03 32 03 / 5 73-0
Telefax: 03 32 03 / 5 73-19

Steuer-Nr.: 020 240 20241
USt-IdNr.: DE 114 193 230
WEEE-Reg.-Nr. DE 81618021
AG Friedberg HRB 5808
Geschäftsführer: Kiichiro Kamiide

The Bank of Tokyo-Mitsubishi UFJ, Ltd. Düsseldorf
Kontonummer: 607 438
Bankleitzahl: 300 107 00
Swift Code: BOTKDEDX
IBAN: DE76300107000000607438

Postbank Frankfurt am Main
Kontonummer: 41 740 609
Bankleitzahl: 500 100 60
Swift Code: PBNKDEFF
IBAN: DE34500100600041740609

Procedure for receiving the software upgrade to the improved software version 02-02:

1. Please inform all potential users in your facility about this Field Safety Notice! For public access AEDs please inform the person responsible for the AED!
2. Please check about the actual location of the AED!
3. Please complete attached receipt "② Receipt of the Field Safety notice (FSN)" and return it by fax or e-mail!
4. Please complete the attached "③ Return Delivery Sheet" and store it to the *cardiolife* AED-2100K. When picking-up the affected unit by the Express courier service please **make sure that this "③ Return Delivery Sheet" is packed together with the AED** to ensure the correct return shipment to you later on!
5. After receiving your receipt your responsible NIHON KOHDEN Representative will contact your specified local contact person for arranging the software update for your potential affected *cardiolife* AED-2100K. An Express pick-up service will collect and return the affected AED for the software update to your next NIHON KOHDEN Service Point for no costs. Please add the "③ Return Delivery Sheet" to the AED-2100K when it picked-up to ensure the fast and correct return after the software upgrade! The software upgrade will be handled with the highest priority and should be finalized within max. 2 working days generally in order to decrease the downtime to the absolute required minimum. Depending on the concrete local situation there might be alternative proceedings for providing the software upgrade by your local NIHON KOHDEN Representative.

The European Competent Authorities are informed about this Field Safety Corrective Action and are monitoring progress and finalization.

If you have any question please do not hesitate to contact your known local NIHON KOHDEN Representative or the European NIHON KOHDEN Headquarter in Germany:

NIHON KOHDEN EUROPE GmbH
Technical Department
Raiffeisenstrasse 10
61191 Rosbach
Germany

Phone: +49 6003 827-160
Fax: +49 6003-827599
E-mail: NKE-SERVICE2@nke.de

We apologize for the inconvenience this Field Safety Corrective Action may cause and thank you for your understanding and co-operation.

Best regards
NIHON KOHDEN EUROPE GmbH
Quality Assurance Department

Attachments: List of affected products
② Receipt of the Field Safety Notice
③ Return Delivery Sheet